



**4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2018-N-1324]**

**Advisory Committee; Science Board to the Food and Drug Administration; Renewal**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the renewal of the Science Board to the Food and Drug Administration (Committee) by the Commissioner of Food and Drugs (Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Board to the Food and Drug Administration for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 26, 2020.

DATES: Authority for the Science Board to the Food and Drug Administration will expire on June 26, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, White Oak Building 1, Rm. 3309, 10903 New Hampshire Ave, Silver Spring, MD 20993, 301-796-4769, [rakesh.raghuwanshi@fda.hhs.gov](mailto:rakesh.raghuwanshi@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Science Board to the Food and

Drug Administration. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Science Board advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility. The Science Board shall provide advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board will provide advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

The Committee shall consist of a core of 21 voting members including a Chair and Co-Chair. The members, Chair, and Co-Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based-products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or

designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Committee may also include technically qualified Federal members. The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements. If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm115356.htm> or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.).

For general information related to FDA advisory committees, please check

<https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 12, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-15297 Filed: 7/17/2018 8:45 am; Publication Date: 7/18/2018]